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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DEPOMED, INC., Plaintiff, v. STRIDES PHARMA, INC. and STRIDES PHARMA GLOBAL PTE LIMITED, Defendants.	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Depomed, Inc. ("Depomed") alleges as follows against Strides Pharma, Inc. and Strides Pharma Global Pte Limited (collectively "Defendants"):

THE PARTIES

1. Plaintiff Depomed is a California corporation, having its principal place of business at 7999 Gateway Boulevard, Suite 300, Newark, California 94560.

2. Upon information and belief, Defendant Strides Pharma, Inc. ("Strides Inc.") is a New Jersey corporation, having a principal place of business at 2 Tower Center Blvd., Suite 1102, East Brunswick, NJ 08816.

3. Upon information and belief, Defendant Strides Pharma Global Pte Limited ("Strides Global") is a Singapore corporation, having a principal place of business at No. 8 Eu Tong Sen Street, #15-93, The Central, Singapore 059818.

4. Upon information and belief, Strides Inc. is an agent or affiliate of Strides Global and is acting on behalf of Strides Global with respect to ANDA No. 210078.

5. Upon information and belief, Strides Inc. and Strides Global regularly transact business within New Jersey, including through Strides Global's direction of the operations and management of Strides Inc., as well as shipping generic drugs to Strides Inc. from locations outside the United States for marketing, sale, and distribution by Strides Inc. within the United States generally, and New Jersey specifically.

NATURE OF THE ACTION

6. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, § 100 et seq., and in particular 35 U.S.C. § 271(e)(2)(A), arising from Defendants filing or causing to be filed Abbreviated New Drug Application ("ANDA") No. 210078 seeking approval to market diclofenac potassium 25 mg oral capsules (Defendants' ANDA Product), which is a generic version of Depomed's ZIPSOR® product, prior to the expiration of U.S. Patent Nos. 7,662,858; 7,884,095; 7,939,518; 8,110,606; 8,623,920; and 9,561,200.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Strides Inc. by virtue of, *inter alia*, Strides Inc.'s corporate presence in New Jersey, its continuous and systematic contacts with New Jersey, and its intent to market, distribute, and/or sell Defendants' ANDA Product in New Jersey.

9. This Court has personal jurisdiction over Strides Global by virtue of, *inter alia*, Strides Global's actions in concert with its affiliate Strides Inc. to file or cause to be filed ANDA No. 210078, Strides Global's continuous and systematic contacts with New Jersey, and its intent to market, distribute, and/or sell Defendants' ANDA Product in New Jersey upon approval of ANDA No. 210078. Further, upon information and belief, Strides Global will derive substantial revenue from the use or consumption of Defendants' ANDA Product in the State of New Jersey.

10. In the alternative, this Court has personal jurisdiction over Strides Global because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met. This Court has jurisdiction over Strides Global because, inter alia, this action arises from actions of Strides Global directed toward New Jersey, and because Strides Global has purposefully availed itself of the rights and benefits of New Jersey law by engaging in continuous and systematic contacts with New Jersey. Upon information and belief, Strides Global regularly and continuously transacts business within the State of New Jersey, including by selling pharmaceutical products in New Jersey, either on its own or through its affiliates. Upon information and belief, Strides Global derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within the State of New Jersey.

11. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

12. U.S. Patent No. 7,662,858 ("the '858 Patent"), entitled "Method of Treating Post-Surgical Acute Pain," issued on February 16, 2010. The '858 Patent is assigned to and owned by Depomed. A copy of the '858 Patent is attached as Exhibit A.

13. U.S. Patent No. 7,884,095 ("the '095 Patent"), entitled "Method of Treating Post-Surgical Acute Pain," issued on February 8, 2011. The '095 Patent is assigned to and owned by Depomed. A copy of the '095 Patent is attached as Exhibit B.

14. U.S. Patent No. 7,939,518 ("the '518 Patent"), entitled "Method of Treating Post-Surgical Acute Pain," issued on May 10, 2011. The '518 Patent is assigned to and owned by Depomed. A copy of the '518 Patent is attached as Exhibit C.

15. U.S. Patent No. 8,110,606 ("the '606 Patent"), entitled "Method of Treating Post-Surgical Acute Pain," issued on February 7, 2012. The '606 Patent is assigned to and owned by Depomed. A copy of the '606 Patent is attached as Exhibit D.

16. U.S. Patent No. 8,623,920 ("the '920 Patent"), entitled "Method of Treating Post-Surgical Acute Pain," issued on January 7, 2014. The '920 Patent is assigned to and owned by Depomed. A copy of the '920 Patent is attached as Exhibit E.

17. U.S. Patent No. 9,561,200 ("the '200 Patent"), entitled "Method of Treating Post-Surgical Acute Pain," issued on February 7, 2017. The '200 Patent is assigned to and owned by Depomed. A copy of the '200 Patent is attached as Exhibit F.

ZIPSOR®

18. Depomed owns approved New Drug Application No. 022202 for diclofenac poteassium capsules, 25 mg, which are sold under the trade name ZIPSOR®.

19. Pursuant to 21 U.S.C. §355(b)(1), the '858, '095, '518, '606, '920, and '200 Patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), in connection with ZIPSOR®.

PRIOR ANDA LITIGATION RELATING TO ZIPSOR®

20. Depomed filed suit in this District against Banner Pharmacaps Inc. and Watson Laboratories, Inc. on July 26, 2013, relating to Banner's ANDA for a generic version of ZIPSOR®. Depomed, Inc. v. Banner Pharmacaps Inc. and Watson Laboratories, Inc., Civil Action No. 2:13-cv-04542 (JLL) (JAD). In that case, Depomed asserted U.S. Patent Nos. 6,287,594; 6,365,180; 7,662,858; 7,884,095; 7,939,518; 8,110,606; and 8,623,920.

21. The Court issued an Opinion construing certain claim terms of the '858 and '095 patents on March 26, 2015.

22. Depomed announced on June 3, 2015, that it reached a settlement agreement with Banner and Watson that permits Watson to begin selling a generic version of ZIPSOR® on March 24, 2022.

23. Judge Linares entered a Consent Injunction and Dismissal Order in Depomed v. Banner on August 25, 2015. Prior to terminating the case, the Court had not adjudicated Depomed's infringement charges or the defendants' defenses and counterclaims.

ACTS GIVING RISE TO THIS ACTION

24. By letter dated March 27, 2017, Defendants informed Depomed "that Strides Pharma, Inc., on behalf of Strides Pharma global Pte Limited (collectively "Strides"), filed a patent certification pursuant to § 505(j)(2)(A)(vii)(IV) of the [Federal Food, Drug and Cosmetic] Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the C.F.R. in support of its Abbreviated New

Drug Application ("ANDA") Number 210078 with respect to diclofenac potassium 25 mg oral capsules."

25. The same letter informed Depomed that "Strides seeks to obtain approval to engage in the commercial manufacture, use or sale of the products for which Strides submitted its ANDA before the expiration of the patents referred to in the certification."

26. According to the same letter, "Strides has certified with the FDA pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) ("Paragraph IV Certification") alleging United States Patents 7,622,858, 7,884,095, 7,939,518, 8,110,606, 8,623,920, and 9,561,200 are invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the proposed Strides product for which Strides has submitted its ANDA."

FIRST CAUSE OF ACTION
(Infringement of the '858 Patent)

27. Depomed realleges and incorporates by reference paragraphs 1-26.

28. Defendants' submission of ANDA No. 210078 to obtain approval to engage in the commercial manufacture, use, and/or sale of Defendants' ANDA Product prior to the expiration of the '858 Patent was an act of infringement under 35 U.S.C. § 271(e)(2)(A).

29. Upon information and belief, Defendants' manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Defendants' ANDA Product prior to the expiration of the '858 Patent will constitute an act of infringement under 35 U.S.C. § 271(a), (b), and/or (c).

30. Upon information and belief, Depomed is entitled to full relief from Defendants' acts of infringement of the '858 Patent under 35 U.S.C. § 271(e)(4).

SECOND CAUSE OF ACTION
(Infringement of the '095 Patent)

31. Depomed realleges and incorporates by reference paragraphs 1-30.

32. Defendants' submission of ANDA No. 210078 to obtain approval to engage in the commercial manufacture, use, and/or sale of Defendants' ANDA Product prior to the expiration of the '095 Patent was an act of infringement under 35 U.S.C. § 271(e)(2)(A).

33. Upon information and belief, Defendants' manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Defendants' ANDA Product prior to the expiration of the '095 Patent will constitute an act of infringement under 35 U.S.C. § 271(a), (b), and/or (c).

34. Upon information and belief, Depomed is entitled to full relief from Defendants' acts of infringement of the '095 Patent under 35 U.S.C. § 271(e)(4).

THIRD CAUSE OF ACTION
(Infringement of the '518 Patent)

35. Depomed realleges and incorporates by reference paragraphs 1-34.

36. Defendants' submission of ANDA No. 210078 to obtain approval to engage in the commercial manufacture, use, and/or sale of Defendants' ANDA Product prior to the expiration of the '518 Patent was an act of infringement under 35 U.S.C. § 271(e)(2)(A).

37. Upon information and belief, Defendants' manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Defendants' ANDA Product prior to the expiration of the '518 Patent will constitute an act of infringement under 35 U.S.C. § 271(a), (b), and/or (c).

38. Upon information and belief, Depomed is entitled to full relief from Defendants' acts of infringement of the '518 Patent under 35 U.S.C. § 271(e)(4).

FOURTH CAUSE OF ACTION
(Infringement of the '606 Patent)

39. Depomed realleges and incorporates by reference paragraphs 1-38.

40. Defendants' submission of ANDA No. 210078 to obtain approval to engage in the commercial manufacture, use, and/or sale of Defendants' ANDA Product prior to the expiration of the '606 Patent was an act of infringement under 35 U.S.C. § 271(e)(2)(A).

41. Upon information and belief, Defendants' manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Defendants' ANDA Product prior to the expiration of the '606 Patent will constitute an act of infringement under 35 U.S.C. § 271(a), (b), and/or (c).

42. Upon information and belief, Depomed is entitled to full relief from Defendants' acts of infringement of the '606 Patent under 35 U.S.C. § 271(e)(4).

FIFTH CAUSE OF ACTION
(Infringement of the '920 Patent)

43. Depomed realleges and incorporates by reference paragraphs 1-42.

44. Defendants' submission of ANDA No. 210078 to obtain approval to engage in the commercial manufacture, use, and/or sale of Defendants' ANDA Product prior to the expiration of the '920 Patent was an act of infringement under 35 U.S.C. § 271(e)(2)(A).

45. Upon information and belief, Defendants' manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Defendants' ANDA Product prior to the expiration of the '920 Patent will constitute an act of infringement under 35 U.S.C. § 271(a), (b), and/or (c).

46. Upon information and belief, Depomed is entitled to full relief from Defendants' acts of infringement of the '920 Patent under 35 U.S.C. § 271(e)(4).

SIXTH CAUSE OF ACTION
(Infringement of the '200 Patent)

47. Depomed realleges and incorporates by reference paragraphs 1-46.

48. Defendants' submission of ANDA No. 210078 to obtain approval to engage in the commercial manufacture, use, and/or sale of Defendants' ANDA Product prior to the expiration of the '200 Patent was an act of infringement under 35 U.S.C. § 271(e)(2)(A).

49. Upon information and belief, Defendants' manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Defendants' ANDA Product prior to the expiration of the '200 Patent would constitute an act of infringement under 35 U.S.C. § 271(a), (b), and/or (c).

50. Upon information and belief, Depomed is entitled to full relief from Defendants' acts of infringement of the '200 Patent under 35 U.S.C. § 271(e)(4).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Depomed respectfully requests the following relief:

1. A judgment that Defendants' submission of ANDA No. 210078 to obtain approval to engage in the commercial manufacture, use, and/or sale of Defendants' ANDA Product prior to the expiration of the '858, '095, '518, '606, '920, and '200 Patents was an act of infringement of those patents under 35 U.S.C. § 271(e)(2)(A).

2. A judgment that Defendants' manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Defendants' ANDA Product prior to the expiration of the '858, '095, '518, '606, '920, and '200 Patents would constitute an act of infringement of those patents under 35 U.S.C. § 271(a), (b), and/or (c).

3. A judgment that the claims of the '858, '095, '518, '606, '920, and '200 Patents are not invalid or unenforceable.

4. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of approval of ANDA No. 210078 shall be a date which is not earlier than the latest expiration date

of any of the '858, '095, '518, '606, '920, and '200 Patents, including any extensions and/or additional periods of exclusivity to which Depomed is or becomes entitled.

5. An order permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants, and employees, and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States, Defendants' ANDA Product until after the expiration of the '858, '095, '518, '606, '920, and '200 Patents, including any extensions and/or additional periods of exclusivity to which Depomed is or becomes entitled.

6. An order declaring this case exceptional under 35 U.S.C. § 285 and awarding Depomed costs, expenses, and disbursements in this action, including reasonable attorney fees.

7. Such further and other relief as this Court deems just and proper.

Dated: May 5, 2017

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Plaintiffs, by their undersigned counsel, hereby certify that the matter in controversy in this action is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: May 5, 2017

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